

JUN 18 1996

K961456

SUMMARY OF SAFETY AND EFFECTIVENESS

The following tests have been completed on an aqueous extract from the RAD-KOTE K261 epoxy coated applicator covered by this 510(k).

1. Primary Dermal Irritation in Rabbits - Not a primary irritant
2. Oral Toxicity in Rats - Non-toxic
3. Subacute Vaginal Irritation in Rabbits - Non-irritating
4. Agar Diffusion Study - No zones of inhibition were seen (Exhibit 6).
5. Toxin Study - Results were in the range of values of commercially sold tampons (Exhibit 7).
6. Repeat Insult Patch Test in Humans - No irritation or sensitization reported
- *7. Dioxin Analysis - Not detectable at limits of detection of HRGG/HRMS Method 8290 (Triangle Labs, North Carolina) (Exhibit 8)
- **8. Lamination Bond Integrity Test - No delamination reported (Exhibit 9)
9. Cytotoxicity Test - No evidence of cell lysis or toxicity was reported.

* Tests conducted on applicator, pledget and string.

** Tests conducted on applicator only.